

SPL Process ER/DL Meeting Meeting Minutes Apr 20, 2016

Chair of today's meeting: Mary Beth Wilusz

Teleconference information:

USA Toll-Free: 866-213-2145

USA Paid/International: 609-454-9913

Access code: 273 8216

Link to the SPL wiki:

<http://spl-work-group.wikispaces.com/share/view/51351516>

Agenda:

1. Dual FEI numbers – any updates?

- In 2008, companies were assigned multiple FEI numbers – especially for foreign sites. I.e. a site had 2 FEI numbers, and FDA was requesting changing to the newer number, potentially different from what was in registrations.
- Who should you contact to correct this?
Information from January meeting minutes:
 - eDRLS office and then forwarded to the ORA office.
 - ORA: Irma Rivera: irivera@ora.fda.gov
 - ORA: Susan Laska: Susan.Laska@fda.hhs.gov
- Any other updates on this?

Meeting discussion: No additional followups

- ### 2. Follow-up from 23-Mar-2016 meeting: Can you ship drug before drug listing. CBER approval letters state “you are approved to ship drug in interstate commerce. (Sandy - Jansen)
- a. How quickly do you have to drug list after approval – ie do you have to drug list before shipping product in interstate commerce?
 - b. Sandy is checking with eDRLS and will let us know what she finds out.

Meeting discussion:

- eDRLS group advised to follow up with CDER group
- CBER letters don't have statement that must drug list within 14 days.
- Most companies follow the CDER guidelines of ASAP after approval
- Other downstream uses – getting on formularies, CMS reimbursement.
- CBER states that have to submit SPL files back to the review division.

3. Market start/end dates at outermost package level (Howard)
 - a. Error: If the document type is under CDER authority, then the marketing start or end date must be present at the outermost package level
 - b. Question: anybody knows why this error pop up if product is OTC under monograph. May be FDA made some requirements in SPL...?
Any suggestions will be greatly appreciated!

Meeting discussion:

- This has been implemented.
- Lonnie is granting overrides, if you send him an email stating the reason.
 - o Tricia is waiting for updates to their software.
- Required for all CDER document types: Rx, OTC, bulk ingredient, bulk for further processing.

4. In the data product elements section of an SPL, specifically the business operations, how many companies are reporting down to pack/repack, label/relabel level? Historically we have reported at this level, but would like to know if others are as well. It appears to me that per the regulations (21CFR, part 207.35), at a minimum only the manufacturer ("...the name of its manufacturer or distributor...") is **required**? (Tricia)

Meeting discussion:

- Most people are reporting down to the pack/label level.
- Manufacturer in the OLD days covered it all, Once we started submitting electronically, guidance said to include the supply chain. Thus, manufacturing is now being reported to different levels -- manufacturer, pack, label, etc.
- Pack is putting product in the primary container. Label is all the other steps to make the final product.
- Repack/relabel is taking product that is already final trade product and subdividing it.

5. Question on alternate image text on DailyMed (see other file for more detail and screen shot examples) -Marlene

Meeting discussion:

- Being entered for American Disability Act
- If there is an image, you describe it briefly "eg image of capsule"
- Purpose of PDP text is searchability and highly readable.

6. (Roberta) There have been several questions about the Kits or Therapy Packs that have unique NDC# but are composed of products already on the market plus alcohol wipes plus needles or a patch plus a topical cream. The company is then submitting to DailyMed the SPL of the individual ingredients-the exact package inserts.
 - o How does the FDA view these products?
 - o Does the Application # apply to the Kit/Therapy Pack or to the individual drug within?
 - o Does the FDA view these Kits/Therapy Packs as "approved products"?

- Why aren't these companies considered repackagers?

Meeting discussion:

- FDA regards these kits as unapproved drug products. Not approved.
- Marketing status is "unapproved drug product"

7. Labeling and NDCs for kit – injector plus desiccant. – two components, 1 active, 1 inactive.
 - a. Active is a nasal inhaler thing. Outer is only a holder that contains desiccant. Should be stored together.
 - b. Do you need to create an NDC code for the outer desiccant part.
 - c. How do you label them – ie label on all 3 parts – ie put two NDCs on the outer desiccant.

Meeting discussion:

- Question: NDCs: how many.
 - 1 active inhaler
 - 1 outer with desiccant
 - 1 kit
- Question: Labeling – what would be on the outer label – desiccant.
- Question: Does the desiccant have to be drug listed.
 - Desiccant is a packaging material. It is not part of the drug product.
 - Some bottles of tablets/capsules have desiccants in it. Not sure whether it included in the drug listing. Don't think so.
 - You might describe the desiccant in the PI. Ie cap includes a desiccant.
 - Ventolin HFA. Has desiccant in the overwrap, not in the cap. They don't list the desiccant at all. GSK

8. Viewing SPL from DailyMed using different browsers (Ann Paradise-Jasniewski, Takeda)– ie getting different view from IE 8 vs IE11 vs Chrome. Also different from viewing from FDA label repository.

Meeting discussion:

- Howard diagnosed the problem. The "new paragraph" is coded as a bullet with a blank bullet. The DailyMed coding apparently gives all bullets a symbol.
- Pat talked to John Kilbourne at DailyMed. He said that they will be changing their coding to accommodate this, but this will take a while.
- The file appears correctly from the FDA label repository (FDA stylesheet) versus the DailyMed.
- There can be differences in opening up stuff in FDA versus DailyMed based on stylesheet.
- Link to the cder direct portal – to get account.
<https://direct.fda.gov>

Ongoing followup items:

Dual FEI numbers – any updates?

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Coming Event: SPL Jamboree 2016: Tuesday Sept 27, 2016